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| 10/072,084 | 02/08/2002 | Jose V. Torres | 3648.032 | 9437 |

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| EXAMINER | |
|---|---|
| WESSENDORF, TERESA D | |
| **ART UNIT** | **PAPER NUMBER** |
| 1639 | |

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/072,084 | TORRES, JOSE V. | |
| | Examiner | Art Unit | |
| | T. D. Wessendorf | 1639 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,10,11,14 and 17-36* is/are pending in the application.

4a) Of the above claim(s) *14 and 17-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 10-11 and 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

***Status of Claims***

Claims 1, 10, 11, 14 and 17-36 are pending

Claims 14 and 17-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1, 10-11 and 32-36 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112, first paragraph***

Claims 1, 10-11 and 32-36, as amended and added, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons advanced in the last Office action, 1/10/2005.

***Response to Arguments***

The Applicant believes that a number of such mixtures are described in the Examples. Specifically, mixtures directed to and the preparation of such mixtures is based directly on the method provided. The Applicant believes that the process described and claimed has wide applicability to a number of pathogens, and does not wish to limit the invention to a particular pathogen. Further, to limit the process for preparing a mixture to the extent that it would recite particular peptides from an exemplary mixture would be overly limiting the invention. Given that process claims have been elected, the Applicant does not now wish to be limited to a particular formulation by being forced to recite sequences.

In response, it is not seen how a peptide can be prepared given no structure of a peptide or even a pathogen from which the epitopic peptide can be derived, especially when the structures of some pathogens have not yet been elucidated. Applicants are not forced to limit the overly broad genus claim. However, applicants should provide adequate written description in the disclosure to be entitled to the broad scope of the genus claim. The description does not provide an indication that the single species described in the specification is applicable or predictive to the broad scope of the genus as claimed.

The Applicant believes that a structural formula is not necessary to enable the making of a peptide mixture. There are exemplary descriptions of the structures of a variety of immunogenic epitopes of a number of pathogens. Further, in the examples provided, it would be clear that identification of common or variable residues would be based on the immunogenic epitope sequences obtained in the step of "obtaining".

In response, a written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials. University of California v. Eli Lilly and Col, 43 USPQ 2d 1398, 1405( 1997), quoting Fiers V. Revel, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993). See also University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003). Applicant fails to point out where the exemplary descriptions of the structures of a variety of immunogenic epitopes for a number of pathogens are found in the specification. Simply reciting the tem "obtaining" does not equate to identifying the structures of a pathogen. It does not disclose which of the structures can be considered the common residues or the length of the common residues to differentiate the common from the variable regions.

The Applicant advises that those skilled in the art would understand how (and where) to obtain information regarding immunogenic epitope sequences for any variety of pathogens. Exemplary sequences are taught for HIV, influenza, and HCV in the application. These pathogens are each the subject of databases maintained and overseen by the National Institutes of Health. It is illogical, therefore, NOT to extend this to other pathogens for having immunogenic epitope sequences.

In reply, it is not controverted that the description is drawn to the exemplary sequences for HIV, influenza and HCV. The issue however, is whether the written description for this specific viral pathogen can be applicable to the numerous different pathogens such as bacterial, fungal or even to the other viral pathogens. While it might not be illogical to extend it to other pathogens, however, the specification has not logically extended the description to other pathogens, besides the three described viral pathogens. Neither does the specification provides reasonable assurance or direction that the three described viral pathogens is logically extendable to other pathogens.

Applicant states that although it is true that numerous pathogens may be or could be used in the method of the invention, the Applicants do not believe that specific sequences

need to be recited, provided a person skilled in the art would know where to find or how to derive such sequences.

In response, the specification does not disclose or provide guidance as how the sequences can be derived for the other pathogens e.g., bacteria or fungi unrelated to the three described viral species. It does not describe what would constitute a common residue(s) or variable residue(s) for a given bacterial pathogen(s). The length or number of what would be considered a common residue(s) region or a variable residue(s) within the common region. Are the length and numbers of the common residue(s) in the three representative examples applicable to the any other type of pathogens? What would be a representative number of a common region for all or any type of pathogens? A representative number of species means that the species, which are adequately described, are representative of the entire genus. The disclosure of only one species (viral, not even a complete viral species) encompassed within a genus adequately describes a claim directed to that genus only if the disclosure indicates that the applicants have invented species sufficient to constitute the gen[us]. Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004).

The Examiner states that synthesis of a peptide requires a structure to enable synthesis, such as for chain lengthening. This is precisely the process that the instant claim set is directed to. The process outlines the steps needed to arrive at the amino acids that are to be added in a chain lengthening procedure.

In response, how can the process of the instant claim be lengthened by synthesis, when the starting peptide sequence is not known or of no defined structure(s).

The Examiner notes that pathogens undergo variability and mutations. It is on the basis of this observation that the instant invention was arrived at. The regions that are common (or conserved) in a pathogen will not show mutations, and for purposes of the claimed process, would be considered "common". However, the variable regions are ones that have variability. This will be evident from the sequences found in the step of "obtaining".

In response, applicant's arguments appear contradictory to the above response i.e., obtaining the sequence from a database i.e., a fixed sequence of a pathogen. How can the process of mutations and variability be the process obtained from the claimed process? The disclosure does not indicate which residues in the pathogens undergo mutations (i.e., in vivo) or which are

conserved by said mutations. Thus, the process of "obtaining" involves numerous process steps for which the single embodied steps described in the specification would not constitute a description for the huge scope of even the single process steps. This not to mention the unstructured compounds employed in the process derivable from a pathogen.

Applicant states that it is true that a pathogen can comprise numerous epitopes, but defining a structure would limit the invention to one specific epitope for one specific pathogen. A person skilled in the art can identify an epitope that has variability, and the Applicants assert that any such epitope could be relied upon to formulate a mixture according to the claimed process. The immunogenicity of such a mixture could then be tested as outlined in the examples of the application.

In reply, true test of any prior art relied on to show or suggest that a chemical compound is old, is whether the prior art is such as to place the disclosed "compound" in the possession of the public. If merely listing compounds could suffice as a disclosure, it would bar patent protection to the person who actually discovered a compound on the list and, in so doing, thwart the Constitutional purpose of the patent system. See in re Wiggins, 488 F.2d 538, 179 USPQ 412(CCPA 1973).

Applicant states that in the step of obtaining, the term "immunogenic epitope sequences" may have caused some confusion for the Examiner. The term is defined by the claim language (see Claim 1), specifically: "said immunogenic epitope sequences having a common residue region and at least one variable residue-". The Applicants believe this is an adequate definition to allow a person skilled in the art to locate an immunogenic epitope sequence from a pathogen. Areas of antigenic variation are **by definition** immunogenic epitopes. It is known in the art, and there is adequate data to support that immunity drives antigenic variation. Thus, wherever variability is observed, this is because an immunogenic region of the sequence was varied or mutated, thereby avoiding detection.

In reply, the whole pathogen can be immunogenic without being necessarily antigenic. If applicant choose to rely upon general knowledge in the art to render his disclosure complete, the appellants must show that anyone skilled in the art would have actually possessed the knowledge, In re Lange (CCPA 1981) 644 F2d 856, 209 USPQ 288. Applicant can rely upon prior art which would enable one skilled in the art to glean therefrom the necessary information to render the specification complete with respect to the first paragraph of 35 USC 112 but the burden is on applicant to point out precisely where description lies in such

disclosure In re Albrecht II (CCPA 1975 ) 185 USPQ 590. However, not every thing, which may be cited as prior art to preclude the grant of a patent can be equated with common knowledge for the purposes of meeting the written description requirement of 112.

The Examiner recites a quote from University of California v. Eli Lilly (1997), but this quote is not relevant to process claims per se since chemical structures.(?) The formulae or chemical names required in that case were relevant to composition of matter claims. The instant claims are process claims. For processes that may be applied in more than one circumstance or with a variety of different materials, the Applicant is not aware of a requirement to recite a particular chemical structure on which the process must be enacted. The Applicant agrees that the process now described and claimed could indeed be relevant to a large number of different pathogens. Exemplary pathogens are discussed (HIV, HCV and Influenza) in adequate detail for a person skilled in the art to apply the process to these or other pathogens. Thus, to restrict the invention to the exemplary embodiments would appear to be unduly limiting when mere substitution of one pathogen for another is all that is required for a person to practice the invention with a non-exemplified pathogen.

In reply, to be entitled to such weight in method claims, the recited structural limitation (herein, no structure is given) therein must ***affect*** the method in a ***manipulative sense*** and not to amount to the mere claiming of a use (making, as claimed) of a particular (compound) structure. (Ex parte Pfeiffer, 782 O.G. 639, 135 USPQ 31 (1961). (Emphasis added.)

Applicant believed that with amendments now in place in Claim 1 that the invention is fully supported.

In reply, even with the amendments to the claims, the language of the genus claim encompasses a huge scope that it causes the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

***Claim Rejections - 35 USC § 112, second paragraph***

New claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "The group of RNA viruses" lack antecedent basis of support from the base claim which does not recite these group of RNA viruses.

***Claim Rejections - 35 USC § 103***

Claims 1, 10-11 and 32-36, as amended and added, are rejected under 35 U.S.C. 103(a) as being obvious over Anderson et al (Vaccine, 1994) for reasons of record.

***Response to Arguments***

Applicant states that Anderson et al do not provide suggestion or motivation (either within the reference itself or generally) that the teachings relating to a process for forming a highly complex mixture having over 32,000 peptides could be modified or extended to arrive at the method now described. There is no motivation provided to reduce the number of peptides in the mixture, as now recited in Claim 1 (from 2 to 64 peptides). Additionally, there is no motivation to employ a rounding step to the nearest 25%. In fact, in Table 1 of Anderson et al., none of the peptides for which two variations of an amino acid are used has been rounded to the nearest 25%. The percentages noted are either 80%:20% or 70%:30%. Not one of the variable residues noted n Table 1 of Anderson et al have an amino acid present at 25%, 50% or 75%, as now specifically indicated in claim 1 as amended. Applicant states that although 80:20 and 70:30 are typical in this paper, there is no suggestion of an inclination to systemize this decision-making process -when deciding on a ratio. Thus, according to Anderson et al, a variety of ratios would be permitted. According to the instant process claimed in amended Claim 1, an amino acid represented in a variable residue at a ratio other than 25%, 50% or 75% would not be permitted.

In reply, Applicant's peptides would amount to a similar, if not the same 32,000 peptides as obtained from the variations or additions of amino acids in the common region without any given structure. How can only two peptide mixtures be obtained from several epitope variations of a given pathogen, especially when the structures of a pathogen is not even known? Furthermore, Table 1 of Anderson as applicant recognized clearly showed specific ratios of 20%, 30%, 80% and so forth of the variable amino acids being added to the peptide sequence. These values are near the claimed 25%. It would be within the ordinary skill in the art to determine the nearest 25% that the residue can be rounded to. For example, 80% is near to 75% or 20-30% near to 25%. As recognized by applicants Anderson teaches a variety of ratios. To determine the workable ratio from those disclosed by the prior art would be obvious to one having ordinary skill in the art at the time of filing. The ratio of Anderson approximates the claims nearest to 25% ratio.

A discovery of an "optimum value" of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch, 205 USPQ 215. Applicant has not shown that to "systemize this decision-making process -when deciding on a ratio" produces new and unexpected results from that of the prior art.

Applicant states that there is no acknowledgement in Anderson et al that a mixture having tens of thousands of different peptides would not be commercially viable. The mixture taught by Anderson et al would function to satisfy academic interests at best, but does not provide a practical solution to the problem of formulating an immunogenic peptide mixture. The Examiner has not produced any other reference that can be combined with Anderson et al to provide the missing features and limitations that are now recited in Claim 1 as amended.

In response, whether the peptide mixtures of Anderson would be commercially viable or would satisfy only academic interests is irrelevant to the finding of obviousness. Applicant's method has not also been found to be commercially viable. Anderson teaches or at least suggests all the claimed limitations. It is deemed unnecessary to use another reference when the single Anderson reference suffices the finding of obviousness.

In view of the amendments to the claims, the 35 USC 102 rejection over Anderson has been withdrawn.

No claim is allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS**

**ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 14 and 17-31 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
July 18, 2005